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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,831

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Thomas R. Kozel

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

09/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,831	Applicant(s) KOZEL ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-19,33,35-37,39-49 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19,33,35-37,39-49 and 51-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 June 2008 has been entered.

Claims 15, 33, 40, and 51 have been amended. Claims 21 and 34 have been canceled.

2. Claims 15-19, 33, 35-37, 39-49, and 51-60 are pending and under consideration.

Rejections Moot or Withdrawn

3. The rejection of amended claims 21 and 34 under 35 U.S.C. 112, second paragraph, as being indefinite for "a level" is moot in light of the cancellation of the claims.

4. The rejection of amended claims 15-19, 33, 35-37, 39-49, and 51-60 under 35 U.S.C. 112, second paragraph, as being indefinite for "a level" is Withdrawn in light of the amendments of the claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Newly amended claims 15-19, 33, 35-37, 39-49, and 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The amendment of claims 15, 33, 40, and 51 results in the claims reading that the presence of soluble PGA, at any level, is indicative of bacterial infection by a PGA producing pathogen in a vertebrate.

The specification, paragraphs 0093 and 0094 recite:

"[0093] In many embodiments, the reference 7DPGA (or 7LPGA) level is an average level of soluble yDPGA (or yLPGA) in blood samples from reference subjects who have not been infected by or exposed to *Bacillus anthracis*. The reference PGA level and the PGA level being compared can be determined using the same or comparable methods. In many other embodiments, the reference yDPGA (or yLPGA) level is an average level of soluble 7DPGA (or 7LPGA) in blood samples from reference subjects who are infected by *Bacillus anthracis*. The reference subjects may be at the same infection or disease stage. The reference subjects may also be selected from different infection or disease stages.

[0094] In one example, the average PGA level in blood samples from *Bacillus anthracis*-free subjects is considered negligible. Thus, a detectable level of soluble PGA in a blood sample from a subject of interest is suggestive of the infection of *Bacillus anthracis*."

Claims originally filed with the specification recite:

21. The method according to claim 19, further comprising comparing the level of said soluble poly glutamic acid in the biological sample to a reference level of said soluble poly glutamic acid.

22. The method according to claim 19, wherein the reference level of said soluble poly glutamic acid is an average level of said soluble poly glutamic acid in blood samples from humans who have not been infected by *Bacillus anthracis*.

The claims indicate that some level of soluble polyglutamic acid is present in humans who have not been infected by a soluble polyglutamic acid producing (*B. anthracis*) bacteria.

The specification indicates that "in one example", the "average" PGA level in blood samples from *B. anthracis* free subjects is considered negligible. The specification does not state that no PGA is present in non-infected humans, only that an "average" is negligible.

Thus, the teachings of the specification and claims, at the time the application was filed, indicate that soluble PGA is present in humans non-infected with a soluble PGA producing bacteria.

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Therefore, the instant claims are unclear how one discriminates between a non-infected subject and a subject infected with a soluble PGA producing bacteria if the presence of soluble PGA is considered a positive result. Such a positive result would apparently pick occur in normal non-infected individuals also.

Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisors, Shannon Foley (571)272-0898, and Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

October 1, 2008